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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,420	07/23/2003	Nancy Auestad	6960USP1	9175

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ROSS PRODUCTS DIVISION OF ABBOTT LABORATORIES
DEPARTMENT 108140-DS/1
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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,420	AUESTAD ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-29 are presented for examination.

Applicant's Amendment filed July 21, 2005 has been received and entered into the application. Accordingly, the specification at pages 20-21 and 27 and claims 1-29 have been amended.

In view of the above amendments and Applicant's remarks at pages 8-11 of the amendment, the objections to the claims and specification and the rejection of claims 18-23 under 35 U.S.C. 112, second paragraph, have each been hereby **withdrawn**.

Claim Rejection – 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6, 10-11, 16-17, 22-23, 26 and 29 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention, for the reasons already made of record at pages 3-4 of the previous Office Action dated March 28, 2005.

Applicant submits that the term "about" is commonly used and legally recognized in U.S. claims as a means to characterize the literal scope of a numeric range. Applicant further submits that the rejection is improper and should be withdrawn.

Applicant's remarks have been carefully considered, but fail to be persuasive in establishing error in the propriety of the present rejection.

In particular, it is noted that the present disclosure fails to guide the skilled artisan in determining the amount of variation above or below the given dose range that is considered within the scope of the present claims. While it is acknowledged that the term "about" is not always indefinite, as asserted by Applicant, each case is decided on its own merits.

In the present case, the use of the term "about" has been determined to be indefinite, despite Applicant's assertion to the contrary. Although Applicant relies on the fact that such a term is commonly used and legally recognized in U.S. claims as a means to characterize the literal scope of a numeric range, the specification does not provide adequate disclosure to define the scope of the term "about", since it fails to direct the skilled artisan to a particular amount of variability above or below the given ranges that is intended to be encompassed by Applicant's invention, and Applicant's remarks provided in the amendment fail to cure this deficiency.

For example, one of ordinary skill in the art may construe the term "about" to indicate a variation in the dose of $\pm$ 8 mg/kg. In such a case, and absent any factual evidence or direction to the contrary by Applicant, such an interpretation could easily read on 0 mg of long-chain polyunsaturated fatty acid (PUFA), i.e., the absence of long-chain PUFA from the composition entirely. While this interpretation may not strictly be the embodiment of the invention that Applicant is intending to claim, such an interpretation is consistent with the MPEP at §2111, which states that words and phrases in the claims must be given their "plain meaning" as understood by one having ordinary skill in the art unless defined by Applicant in the specification with "reasonable clarity, deliberateness and precision" (MPEP §2111.01). Absent any disclosure delineating the degree of variation intended to be within the scope of the term, the word "about" is, therefore, considered indefinite in the present case.

Rejection of claims 5-6, 10-11, 16-17, 22-23, 26 and 29 is proper and is **maintained**.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-29 remain rejected under 35 U.S.C. 102(a) as being anticipated by Jandacek et al. (International Publication No. WO 02/00042 A2; January, 2002), already of record, for the reasons of record as set forth in the previous Office Action dated March 28, 2005 at pages 6-13.

Applicant's remarks at pages 9-10 of the amendment filed July 21, 2005 have been carefully considered, but fail to be persuasive in establishing error in the propriety of the present rejection.

Applicant states that Jandacek et al. discloses compositions comprising satiety agents selected from long chain fatty acids and their non-glyceryl esters, hydrolysable in the presence of gastro-intestinal enzymes, wherein the satiety agent releases in the stomach and excludes the use of triacylglycerols as satiety agents, noting that triacylglycerols are hydrolyzed in the small intestine rather than the stomach and, thus, have little effect on food intake. Applicant further submits that since Jandacek et al. fails to disclose all of the limitations of Applicant's broadest claims.

Although Applicant *asserts* that Jandacek et al. expressly excludes the use of triacylglycerols, such a teaching cannot be located in the reference. Applicant's reliance on the disclosure of Jandacek et al. at page 3, lines 27-33 and page 5, lines 12-15 has been considered in support of their position, but does not constitute an express exclusion of the triacylglycerol form of long chain fatty acids as the satiety agent of the disclosed invention.

The mere statement that, "Little of these reach the liver in the form of long chain non-esterified fatty acids during the course of a meal and thus influence food intake" does not amount to an express exclusion of the use of triacylglycerols, nor does it constitute an express statement that the use of triacylglycerols will have absolutely no effect whatsoever on dietary intake. While the use of such may constitute a non-preferred embodiment, insofar as the effect that such an agent(s) has on dietary intake may not be as great as a non-glyceryl ester of a long-chain fatty acid, such does not change the fact that the reference expressly discloses the use of long-chain fatty acids, specifically, docosahexaenoic acid or arachidonic acid (see Jandacek et al. at page 6, last paragraph), as the satiety agents to be administered. As stated in Jandacek et al., essentially all long chain fatty acids found in the diet are ingested in the form of triacylglycerols (see page 5, lines 5-7). Thus, the very nature of administering a long-chain fatty acid would result in the direct administration of the triacylglycerol form of the fatty acid.

Regarding non-preferred embodiments, the MPEP states at §2123, "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments...**Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments**." (emphasis added) Thus, although Jandacek et al. recognizes that the administration of a

triacylglycerol may have reduced efficacy in appetite modulation and effect on obesity than the administration any other form of long-chain fatty acid, such as a non-glyceryl ester of a long-chain fatty acid, such is not considered to constitute a teaching away from this embodiment of the invention.

In further response thereto, it is again noted that the long-chain fatty acid satiety agent is administered anywhere from 30 minutes prior to or 6 hours prior to the consumption of food (see page 8, first paragraph), such that administration "prior to subsequent consumption of food so as to induce a sensation of satiety in the subjects for a sufficient time wherein the amount of food subsequently consumed is reduced, thus reducing total caloric intake by controlling the subject's appetite" (see page 6, lines 18-22). While Jandacek et al. acknowledges that, "Little of these reach the liver in the form of long-chain non-esterified fatty acids during the course of a meal and thus influence food intake", the very fact that the fatty acid(s) may be administered well before a meal allows sufficient time for the amount of triacylglycerols that *do* reach the liver to exert their effect on appetite modulation and influence food intake prior to meal consumption, thereby effecting reduced dietary consumption.

In light of the above remarks and those previously made of record, rejection of claims 1-29 is proper and is **maintained**.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

> matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 and 18-23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jandacek et al. (International Publication No. WO 02/00042), already of record, for the reasons of record set forth in the previous Office Action dated March 28, 2005 at pages 13-14.

Applicant's remarks at pages 10-11 of the amendment filed July 21, 2005 have been carefully considered, but fail to be persuasive in establishing error in the propriety of the present rejection.

Applicant states that Jandacek et al. discloses compositions comprising satiety agents selected from long chain fatty acids and their non-glyceryl esters, hydrolysable in the presence of gastro-intestinal enzymes, wherein the satiety agent releases in the stomach and excludes the use of triacylglycerols as satiety agents, noting that triacylglycerols are hydrolyzed in the small intestine rather than the stomach and, thus, have little effect on food intake. Applicant further submits that Jandacek et al. fails to suggest the use of any triacylglycerols and that the reference

actually teaches away from the present invention by stating that triacylglycerols will have little effect on food intake. Applicant relies on an animal study in support of their position.

Applicant's attention is directed above to the remarks presented under "Claim Rejection-35 U.S.C. 102" in response to Applicant's assertion that the Jandacek et al. reference teaches away from the present invention.

Applicant's argument that Jandacek et al. fails to suggest the use of any triacylglycerol is further noted to be in direct contrast to Applicant's remarks at pages 9-10, where Applicant states that Jandacek et al. in fact excludes the use of triacylglycerols from the disclosed invention. Thus, Applicant's position is unclear and is, therefore, not considered persuasive.

While the results of the animal study provided by Applicant in the present amendment and application have been considered, such information is not considered to distinguish the presently claimed subject matter over that of the reference because it fails to demonstrate results that would not have been reasonably expected from the teachings of Jandacek et al. While Jandacek et al. acknowledges that a triacylglycerol may not have the same level of efficacy as a non-glyceryl ester of a long-chain fatty acid, such does not amount to an express statement that the use of triacylglycerols will have absolutely no effect whatsoever on dietary intake. In light of such, the skilled artisan would have reasonably expected that the administration of a triacylglycerol would show some degree of efficacy in modulating food consumption. Applicant's data merely supports the conclusion that the skilled artisan would have expected and does not support the position that such results would have been unexpected or out of the ordinary.

In light of the above remarks and those previously made of record, rejection of claims 1-11 and 18-23 is proper and is **maintained**.

Conclusion

Rejection of claims 1-29 is deemed proper and is **maintained**.

No claims of the present application are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

September 27, 2005

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